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BIOMET SPORTS MEDICINE

MAY - 3 2011

510(k) Summary

Preparation Date: April 13, 2011

Applicant/Sponsor: Biomet Sports Medicine

Contact Person: Elizabeth Wray / Regulatory Project Manager
Victor Rodgers / Director of Quality, Clinical, & Regulatory Affairs
(574) 267-6639

Proprietary Name: Biomet Sports Medicine Sternal Closure System

Common Name: Sternal Closure System

Classification Name: Cerclage, Fixation (21CFR §888.3010) JDQ

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K931271 and K946173	Ethi-Pack Surgical Stainless Steel Suture
K930015 and K013059	Stony Brook Sterna-wire / Sterna-Band™
K011076 and K063506	SternaLock™ Rigid Sternal System / Lorenz Sternal Closure System

Device Description:
The Biomet Sternal Fixation Devices System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures to aid in the alignment and stabilization of bone. The Implants for this application include Clips and ZipLoop™ constructs packaged with single use instruments to assist in insertion and applying tension to close the ZipLoop™ construct to the desired size. The Biomet Sternal Fixation System Devices are single use.

Intended Use:
The Biomet Sports Medicine Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Summary of Technologies:
The technological characteristics (materials, design, sizing and indications) of the Biomet Sports Medicine Sternal Closure System are similar or identical to the predicate devices or

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Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

other previously cleared devices.

Non-Clinical Testing:
Non-clinical laboratory testing was performed to verify the fixation strength of the Biomet Sports Medicine Sternal Closure System in cyclic fatigue testing as compared to the predicate devices for specific indications for use. The efficacy of the Biomet Sports Medicine Sternal Closure System was compared to that of the Ethicon Surgical Stainless Steel Sutures. The test results indicate that the Biomet Sports Medicine Sternal Closure System provide equivalent cyclic fatigue strength to the predicate devices and would be functional within their intended use.

Clinical Testing:
None provided as a basis for substantial equivalence. .

DLG 5/4/11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Sports Medicine
% Ms. Elizabeth Wray
Regulatory Project Manager
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46587

MAY - 3 2011

Re: K110039
Trade/Device Name: Biomet Sports Medicine Sternal Closure System
Regulation Number: 21 CFR 888.3020
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: April 13, 2011
Received: April 14, 2011

Dear Ms. Wray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

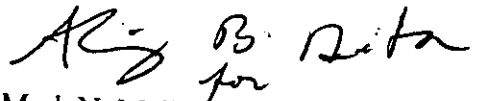
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110039

Device Name: Biomet Sports Medicine Sternal Closure System

Indications For Use:

The Biomet Sports Medicine Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110039